

EPA/OPP MICROBIOLOGY LABORATORY  
ESC, Ft. Meade, MD

Standard Operating Procedure  
for  
OPP Microbiology Laboratory Training Program

SOP Number: ADM-04-00

Date Revised: 08-23-02

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Print Name: \_\_\_\_\_

Laboratory Director

Date Issued: \_\_\_\_/\_\_\_\_/\_\_\_\_

Withdrawn By: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

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1.0 SCOPE AND APPLICATION:

- 1.1 This protocol describes the requirements for education, experience, and training of each OPP Microbiology Laboratory employee in order to ensure that testing and other laboratory procedures are performed by qualified individuals.

2.0 DEFINITIONS:

- 2.1 GLP = Good Laboratory Practices
- 2.2 SOP = Standard Operating Procedure
- 2.3 OPP = Office of Pesticide Programs
- 2.4 EPA = Environmental Protection Agency
- 2.5 SHEM = Safety, Health and Environmental Management
- 2.6 CDC = Centers for Disease Control
- 2.7 NIH = National Institute of Health

3.0 HEALTH AND SAFETY:

- 3.1 Laboratory Scientists and Technicians must complete an initial 24 hour training seminar and an 8 hour refresher course every year thereafter. The SHEM Manager is responsible for providing this training.
- 3.2 Laboratory Scientists and Technicians must undergo a physical exam every year. In addition, Laboratory Scientists and Technicians must receive a Hepatitis B vaccination and undergo a PPD test for Tuberculosis in order to work in the OPP Microbiology Laboratory.
- 3.3 If specific personal protective equipment such as respirators are required, the Laboratory Scientist or Technician must be certified.
- 3.4 In accordance with the CDC/NIH guidelines, the Laboratory Director may restrict access to the laboratory as specified under "special practices".

- 3.5 Laboratory Scientists and Technicians receive biosafety refreshers as necessary (due to audit findings, recommendations from SHEM manager, etc.).
- 4.0 CAUTIONS: None
- 5.0 INTERFERENCES: None
- 6.0 PERSONNEL QUALIFICATIONS:
- 6.1 Good Laboratory Practices (GLP) state that employees shall have education, training, and experience, or any combination thereof, that will enable them to perform the functions assigned to them.
- 6.2 Laboratory Scientists must meet the minimum qualifications set forth in the Operating Manual for Qualification Standards for General Schedule Positions: Individual Occupational Requirements for GS-403: Microbiology Series which is a minimum of 20 semester hours in microbiology or related studies and 20 semester hours in the physical and mathematical sciences combining course work in organic chemistry or biochemistry, physics and college algebra, or their equivalent (see ref. 15.4).
- 6.3 Laboratory Technicians must meet the minimum qualifications set forth in the Operating Manual for Qualification Standards for General Schedule Positions: Individual Occupational Requirements for GS-404: Biological Science Technician Series which is a minimum of 24 semester hours in scientific or technical courses such as biology, chemistry, statistics, entomology, animal husbandry, botany, physics, agriculture or mathematics with at least 6 semester hours in microbiology or related studies (see ref. 15.4).
- 7.0 SPECIAL APPARATUS AND MATERIALS: None
- 8.0 INSTRUMENT OR METHOD CALIBRATION: Not applicable
- 9.0 SAMPLE HANDLING AND STORAGE: Not applicable
- 10.0 PROCEDURE AND ANALYSIS:

- 10.1 Qualifications. Laboratory Scientists and Technicians may perform, without supervision, only those procedures for which they are qualified, as determined by the Laboratory Director or their designate. Qualifications to perform assays and other procedures will be documented in each employee's training record.
- 10.2 Training Responsibilities. The Laboratory Director has overall responsibility to ensure that the staff in the OPP Microbiology Laboratory are adequately trained for their assigned tasks. The Laboratory Director or their designate will train employees to perform assays and other procedures, using the OPP Microbiology SOPs and other appropriate training materials. Upon hire, and annually thereafter, the Laboratory Director or their designate will identify and document the training needs of each employee.
  - 10.2.1 Each Laboratory Scientist and Technician is responsible for checking to determine that they have received appropriate training (including safety training) before beginning any assigned task.
  - 10.2.2 Trainers must verify the proficiency of individuals they train and document this proficiency by initialing the trainee's training record.
  - 10.2.3 Trainees must make sure that they understand the information being communicated to them. They should ask questions about anything they do not understand which might compromise the performance of a task. The "Training Complete" box on the Personnel Training Record (see 16.1) means the employee fully understands the procedure and can perform it properly without supervision.
- 10.3 New Employee Training. New employees will receive a comprehensive introduction to the EPA and OPP Microbiology Laboratory during the first several weeks of their employment. Initial training includes:
  - 10.3.1 Documentation of education and previous work experience. All new employees will document their relevant experience in their curriculum vitae or resume.

- 10.3.2 Familiarization with administrative and personnel policies and procedures by Human Resources or their designate, including the current version of the EPA Employee Handbook of Benefits and Policies.
- 10.3.3 An introduction to the EPA and its clients by the Laboratory Director or designate, including the mission statement, program goals and organizational charts.
- 10.3.4 An overview of the OPP Microbiology Laboratory, including job description and staff responsibilities, training procedures, documentation, and filing systems and their locations.
- 10.3.5 An introduction to testing and laboratory equipment, including the importance of equipment maintenance and calibration.
- 10.3.6 A tour of the Environmental Science Center Facility, which will cover security procedures and the locations of certain areas and equipment. These include: the lunchroom, library, copy machine room, fire extinguishers, bathrooms, fire alarm pulls, eye wash stations and emergency exits.
- 10.3.7 A health and safety examination and overview, including an introduction to MB-01, Biosafety in the Laboratory.
- 10.3.8 A regulatory overview by Quality Assurance Unit (QAU) or their designate emphasizing compliance with Good Laboratory Practices (GLP). This training includes:
  - Why GLPs are required.
  - The role of EPA in the enforcement of GLPs.
  - The significance and use of laboratory generated data.
  - The importance of following standard operating procedures in order to ensure the use of proper methods and test reproducibility.

The need for accuracy and detail in the recording of all data.  
The process for peer review of all official data.

The need to provide traceability in all aspects of the testing process, i.e. sample identification and lot number, test performed, test date, test results.

- 10.3.9 Training will be documented on the Personnel Training Record (see 16.1) as it is performed. For each new employee, the Quality Assurance Unit or their designate will audit the Personnel Training Record approximately 60 days after the hire date for completion of initial training.

10.4 Technical Training. Each new employee will be familiarized with their job description by the Laboratory Director or their designate. Laboratory based training is required for all testing procedures, equipment operation, calibration, and maintenance; quality control activities; sample-log-in and report preparation. Technical training will encompass the following steps:

- 10.4.1 The trainee reads the SOP in which they are being trained.
- 10.4.2 The trainer demonstrates the procedure, explaining the reason for each step of the procedure and the details on how to perform it.
- 10.4.3 The trainee performs the procedure under the supervision of the trainer one to three times or more if needed.
- 10.4.4 When both the trainer and trainee are satisfied that the trainee has achieved proficiency, the trainer initials the "Training Complete" box on the Personnel Training Record (see 16.1).

10.5 Ongoing Training:

- 10.5.1 SOP Review. All Laboratory Scientists and Technicians will review appropriate SOPs when revised. SOP reviews will be documented in the OPP Microbiology SOP Familiarization Record (see 16.2).

- 10.5.2 GLP Training. GLP training will be conducted periodically by the Office of Compliance Monitoring or their designate.
- 10.5.3 Health and Safety Training. Requirements for ongoing health and safety training are specified in the Chemical Hygiene Plan (CHP) and the Safety, Health and Environmental Management Plan (SHEMP).
- 10.5.4 Other Internal Training. The Laboratory Director, Quality Assurance Unit, or senior management may require additional training on specific types of equipment, methods or techniques.
- 10.5.5 On an annual basis, either through a formal employee review or informally in a meeting, the Laboratory Director or their designate will evaluate and document the ongoing training needs for each employee.
- 10.5.6 Continuing Education. The Office of Pesticide Programs encourages appropriate continuing education for all staff to meet program objectives. Continuing education is available through participation in professional associations, trade organizations, and federal and academic institutions. Workshops and focused training are available as mission related initiatives change.
- 10.5.7 Professional Memberships. The OPP Microbiology Laboratory personnel are encourage to pursue appropriate professional memberships, such as ASM (American Society for Microbiology) and AOAC (Association of Official Analytical Chemists') International.
- 10.5.8 Ongoing training will be documented on the Personnel Training Record (see 16.1).
- 10.6 Verification of Competency:
  - 10.6.1 The trainer who signs the Personnel Training Record (see 16.1) of a trainee for a particular SOP is responsible for verifying the competency of that person to perform that



procedure. Trainees should not request a sign off on an SOP until they are fully confident of their ability to perform the procedure without supervision. Where appropriate, trainers may use other means of verifying training efficacy such as workshops and proficiency exercises.

10.7 Qualification of Trainers:

10.7.1 To train another employee on a procedure, a trainer must have:

- a) A current sign-off for the procedure on their Personnel Training Record (see 16.1).
- b) A current sign-off on the procedure and any supporting SOPs on the SOP Familiarization Record (see 16.2).

10.7.2 Management may evaluate and approve individuals for test procedures based on relevant prior experience and education.

10.8 Updating Training Records:

10.8.1 When new or newly revised SOPs are issued, copies are issued to the appropriate employee(s). Each employee is required to read the SOP and update the SOP Familiarization Record (see 16.2).

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Training records for all personnel will be stored in labeled binders in the D217 (Archive Room).

13.0 QUALITY CONTROL:

13.1 The OPP Microbiology Laboratory conforms to 40 CFR Part 160, Good Laboratory Practices.

13.2 For quality control purposes, the required information is documented on the appropriate form(s) (see 16.0).

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 Any deviations from this standard protocol must be documented on a nonconformance memo and corrective action applied if warranted.

15.0 REFERENCES:

15.1 US EPA Good Laboratory Practices, Title 40 Code of Federal Regulations (CFR) Part 160.

15.2 LaSota, Leo. 2000. Quality Assurance Management Plan For The Office of Pesticide Programs Microbiology Laboratory at the Environmental Science Center Fort Meade, MD.

15.3 Richmond, J.Y. and McKinney, R.W. eds. 1999. Biosafety in Microbiological and Biomedical Laboratories. HHS Publication No. (CDC) 93-8395. U.S. Government Printing Office, Washington, D.C.

15.4 U.S. Office of Personnel Management. Operating Manual for Qualification Standards for General Schedule Positions. OPM Publications No. HX118 ([www.opm.gov/qualifications/index.htm](http://www.opm.gov/qualifications/index.htm)).

16.0 FORMS AND DATA SHEETS:

16.1 Personnel Training Record

16.2 Standard Operating Procedures Familiarization Record

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Personnel Training Record  
US EPA, Office of Pesticide Program  
Microbiology Laboratory  
Environmental Science Center, Ft. Meade, MD

NAME OF TRAINEE: \_\_\_\_\_

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# Standard Operating Procedures Familiarization Record

## OPP Microbiology Laboratory

The following Standard Operating Procedures (SOPs) describe accepted methodology for the performance of disinfectant efficacy tests and associated quality control activities. After you have read the various SOPs, sign your initials and date in the space provided to verify that you have read and understand the directions in the SOPs. If you have any questions or require clarifications, do not sign your initials until you have resolved the issue(s) with the team leader or lab director.

[illegible]